Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

225 14 215

RE: Notification of structure/function statements on dietary supplement product GASTRONORM, marketed by TOMIL HERB INC.

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. § 343(r)(6), notification is submitted for structure/function statements appearing on the label and/or in labeling of the dietary supplement product GASTRONORM.

NAME / ADDRESS OF DISTRIBUTOR	TOMIL HERB INC
NAME / ADDRESS OF DISTRIBUTOR	
	291 St. Lawrence Dr., Welland
	ON L3C 7H7, Canada
STATEMENTS	Beneficial for the functioning of a healthy digestive
	tract. It helps soothe occasional stomach or
	intestinal discomfort.*
DISCLAIMER	*These statements have not been evaluated by
	the Food and Drug Administration. This
	product is not intended to diagnose, treat, cure
	or prevent any disease.
DIETARY INGREDIENTS	Spearmint (leaf)
	Anise (fruit)
	Calendula (flower)
	Chicory (stem and leaf)
	Coriander (fruit)
	Flax (seed)
	Alfalfa (stem)
	Centaury (stem and leaf)
	Dill (seed)
	Lemon Balm (leaf)
	Licorice (root)
	Plantain (leaf)
	Yellow Sweetclover (leaf)
DIETARY SUPPLEMENT PRODUCT NAME	GASTRONORM

The undersigned certifies that the information contained in this notice is complete and accurate, and that TOMIL HERB INC has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions or need any additional information, please contact the undersigned at (289)-241-3629.

Sincerely.

George Manolov Director of Marketing TOMIL HERB INC

Enclosures

Certified Mail - Return Receipt Request

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